TORNIER

K070787

AUG 2 4 2007

Summary of Safety and Effectiveness information
Special 510(k) Premarket Notification – Latitude Tornier Elbow Prosthesis

Regulatory authority: Safe Medical Devices Act of 1990, 21 CRF 807.92

1) Device name

Trade name:	***Latitude Elbow Prosthesis***
Common name:	Elbow Prosthesis
Classification name:	Elbow joint metal/polymer semi-constrained cemented prosthesis Elbow joint metal/metal or metal/polymer constrained cemented prosthesis
Classification number:	888.3160 and 888.3150

2) Submitter

Tornier
Rue Doyen Gosse
38330 Saint Ismier - France

3) Company contact

Tornier
Mrs Mireille Lémery
Regulatory affairs Manager
161, rue Lavoisier - Montbonnot
38334 Saint Ismier Cedex - France
Tel: 00 33 4 76 61 38 98
Fax: 00 33 4 76 61 35 33
e-mail: mireille.lemery@tornier.fr

4) Classification

Device class:	Class II
Classification panel:	Orthopedic
Product code:	JDB and JDC

5) Equivalent / Predicate device

Tornier Elbow Prosthesis, Tornier, K000003, K011567, K031218 and K050848

6) Device description

Total Elbow replacement is used to treat a number of clinical conditions such as severe pain or significant disability in degenerative, rheumatoid or traumatic disease of the elbow joint. It is also used in revision procedures where other treatments or devices have failed and treatment of fractures that are unmanageable using other techniques. The usual goal of such surgery is to restore the

TORNIER
161 rue Lavoisier. Montbonnot. 38334 SAINT-ISMIER Cedex. France
Tél. : 33(0)4 76 61 35 00 Fax : 33 (0)4 76 61 35 33 www.tornier.com
SAS au capital de 288 000 €. SIRET 070 501 275 000 13. R.C.S. Grenoble 070 501 275. Code APE 331 B
Siège social : chemin Doyen Gosse. 38330 Saint-Ismier. France

elbow joint to its best working condition and to reduce or eliminate pain. The Latitude Tornier Elbow Prosthesis is intended to accomplish these goals. The Tornier Elbow prosthesis is intended for use as a cemented total elbow.

The Latitude Tornier Elbow Prosthesis is a 3-part system consisting of a humeral, an ulnar and a radial component. The humeral implant is modular and consists in the assembly of various sizes of humeral stem and humeral spool in order to better reproduce the functionality of the natural humerus.
The prosthesis is a non-constrained prosthesis and when it is used with the ulnar cap the prosthesis becomes a semi-constrained prosthesis.

The present device submission corresponds to a modification in the assembly of the humeral stem with the humeral spool. Included in the modification the material of the ring stop has changed from UHMWPE to PEEK-OPTIMA. The radial components and the ulnar components are not modified. The technological characteristics (design, materials, manufacturing, sterilization, sizing and indications) of the modified humeral stem, humeral spool and humeral screw components are similar or identical to the predicate devices.

7) Materials
The humeral stem is available in CoCr alloy. The humeral spool is available in CoCr alloy and PEEK-OPTIMA polymer. The humeral screw is available in stainless steel. The radial components are made of CoCr alloy and UHMWPE. The ulnar components are made of CoCr alloy and UHMWPE.

8) Indications
The *Tornier Elbow Prosthesis* is intended for total elbow arthroplasty. Prosthetic replacement with this device may be indicated to relieve severe pain or significant disability following the effects of primary or secondary osteoarthtitis and rheumatoid arthritis; correction of functional deformities; revision procedures where other treatments or devices have failed; treatment of fractures that are unmanageable using other techniques.
The *Tornier Elbow Prosthesis* is intended for cemented use only.

TORNIER
161 rue Lavoisier. Montbonnot. 38334 SAINT-ISMIER Cedex. France
Tél. : 33(0)4 76 61 35 00 Fax : 33 (0)4 76 61 35 33 www.tornier.com
SAS au capital de 288 000 €. SIRET 070 501 275 000 13. R.C.S. Grenoble 070 501 275. Code APE 331 B
Siège social : chemin Doyen Gosse. 38330 Saint-Ismier. France

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Tornier
% Mrs. Mireille Lémery
Regulatory Affairs Manager
161, rue Lavoisier - Montbonnot
38334 Saint Ismier Cedex - France

AUG 2 4 2007

Re: K070787
Trade/Device Name: Latitude Elbow Prosthesis
Regulation Number: 21 CFR 888.3160
Regulation Name: Elbow joint metal/polymer semi-constrained prosthesis
Regulatory Class: II
Product Code: JDB, JDC
Dated: July 20, 2007
Received: July 25, 2007

Dear Mrs. Lémery:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070787

Device Name: Latitude Tornier Elbow Prosthesis

Indications For Use:

The Tornier Elbow Prosthesis is intended for total elbow arthroplasty. Prosthetic replacement with this device may be indicated to relieve severe pain or significant disability following the effects of primary or secondary osteoarthtitis and rheumatoid arthritis; correction of functional deformities; revision procedures where other treatments or devices have failed; treatment of fractures that are unmanageable using other techniques.
The Tornier Elbow Prosthesis is intended for cemented use only.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070787